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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/667,921

09/22/2003

Ioana M. RizoIU

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10/16/2008

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EXAMINER

SHAY, DAVID M

ART UNIT

PAPER NUMBER

3769

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 10/667,921	<b>Applicant(s)</b> RIZOIU ET AL.	
	<b>Examiner</b> david shay	<b>Art Unit</b> 3735	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED September 22, 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☒ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: none.
- Claim(s) objected to: none.
- Claim(s) rejected: 39-48, 52-59, 65-69 and 76-80.
- Claim(s) withdrawn from consideration: none.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_
13. ☒ Other: See Continuation Sheet.

/david shay/  
Primary Examiner, Art Unit 3735

Continuation of 3. NOTE: Incorporation by reference of disclosures other than that of 09/188,072 is new matter.

Continuation of 13. Other: With regard to the drawing objection, the drawing objection has been maintained due to the apparent reliance by applicant on the particular visualization capabilities that the imager is specifically claimed e.g. in claim 74 to be adapted to do, which are not clearly illustrated in the drawing. With regard to the priority claim, as already set forth in the previous office action, the requirements of 35 U.S.C. 120 are quite explicit: "An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application. No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section." Note especially that the application "must contain specific reference to the earlier filed application" and that the amendment must be submitted "at such time during the pendency of the application as required by the Director. The examiner apologizes if his assumption that applicant was aware of the laws and rules of patent practice as set forth in the MPEP, specifically in MPEP 201.11, in which 37 C.F.R. 1.78 is reproduced, which states, in pertinent part, "this reference must also be submitted within the later of four months from the actual filing date of the later filed application or 16 months from the filing date of the later filed application" see 37 C.F.R. 1.78(a)(2)(ii). Thus, the attempt to include the provisional application 60/064,465, filed November 6, 1997 for the first time in the amendment filed February 8, 2006, is improper as the 99 month period between the filing date of the earlier filed (i.e. the provisional) application and the later filed (i.e. the instant) application is clearly greater than the 16 month period referred to in 37 C.F.R. 1.78(a)(2)(ii), similarly, the 29 month interval between the February 8, 2006 submission and the September 22, 2003 filing date of the instant application is greater than the 4 month period referred to in 37 C.F.R. 1.78(a)(2)(ii). While the examiner was attempting to notify applicant that through a clearly inadvertent omission, the applications intervening the instant application and application serial number 10/188,072 this was not a blanket invitation to alter the priority of the instant application at will, nor was it, even if this were not in contravention of 35 U.S.C. 112, first paragraph, an invitation to incorporate by reference several documents which were never part of or referred to in the originally filed disclosure. Again, the examiner apologizes if an over familiarity of Title 35 of the United States Code; Title 37 of the United States Code of Federal Regulations; or the Manual of Patent Examining Procedure on the part of applicant was assumed, and the examiner will make every effort to even more thoroughly explain the intricacies of these resources. For example, the procedure for taking of official notice is set forth in MPEP 2144.02 under the heading "PROCEDURE FOR RELYING ON COMMON KNOWLEDGE OR TAKING OFFICIAL NOTICE", however since applicant appears to be either unaware of, unable to consult, or unwilling to consult the MPEP, the portion of this particular document with respect to the taking of official notice will be more thoroughly explained. Specifically MPEP 2144.02 states that it is not "unreasonable for the examiner in a first Office action to take official notice of facts by asserting that certain limitations in a dependent claim are old and well known expedients in the art without the support of documentary evidence provided the facts so noticed are of notorious character and serve only to 'fill in the gaps' which might exist in the evidentiary showing made by the examiner to support a particular ground of rejection" this is precisely the case here. In the first action on the merits of the instant case, mailed September 13, 2005, in the paragraph spanning the pages numbered 3 and 4 in that office action, it was stated "in either case, to employ the method on and configure the device for removal of fat tissue in joints or the abdomen, since these are known sites of fat tissue, official notice of which is hereby taken, to employ sterile fluids, since this prevents infection when operating on internal tissue, official notice of which is hereby taken, to construct the device from medical grade plastics, since this is a notorious material for medical devices, official notice of which is hereby taken, and to construct the device of stainless steel, since this is a notorious material for medical devices and is inert, official notice of which is hereby taken" this phrase is completely in keeping with the requirement set forth in section (B) under the aforementioned heading, which requires that the technical line of reasoning underlying a decision to take notice be clear and unmistakable, and was repeated verbatim in both the non-final rejection mailed April 26, 2006 and the final office action mailed December 20, 2006. In response to the first office action, applicant merely argued that the claims were allowable because the combination did not teach all the limitations of the claims, and asserted that the independent claims were allowable and that the dependent claims were at least allowable by virtue of dependency on an allowable independent claim. These statements by applicant are insufficient to constitute a proper challenge to the examiner's taking of official notice. As is clearly stated in section (C) under the aforementioned heading: "To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art." and further states "A general allegation that the claims define a patentable invention without any reference to the examiner's assertion of official notice would be inadequate" in fact applicant's current statement that examiner's determinations "are challenged, traversed, and by no means admitted to be prior art" are also insufficient, as there is no statement of why the noticed facts are not considered to be well known in the art. Lastly, section (C) states "If applicant does not traverse the examiner's assertion of official notice or applicant's traverse is not adequate, the examiner should clearly indicate in the next Office action that the common knowledge or well-known in the art statement is taken to be admitted prior art because applicant either failed to traverse the examiner's assertion of official notice or that the traverse was inadequate. If the traverse was inadequate, the examiner should include an explanation as to why it was inadequate". Assuming applicant regards the examiner's statement in the final office action as deficient in this regard, the foregoing is clearly in compliance with 2144.03(C). This having been done, the examiner reiterates the statement set forth in the final office action: "The examiner has taken official notice of the obviousness of configuring devices for and using devices for the removal of fat tissue in joints or the abdomen, since these are known sites of fat tissue; to employ sterile fluids, since this prevents infection when operating on internal tissue; to construct the device from medical grade plastics, since this is a notorious material for medical devices; and to construct the device of stainless steel, since this is a notorious material for medical devices and is inert" thus, as applicant's traverse of the examiner's taking of official notice is not adequate, the officially noticed facts are taken to be prior art, as sanctioned by

MPEP 2144.03(B) and (C). The foregoing aside, just to be sure the examiner is clear on applicant's position, applicant appears to be asserting, among other things, that the use of medical grade plastics in medical devices is not prior art, and thus was first conceived of by applicant, and was not known to practitioners of the art of constructing medical devices, to the best applicant's knowledge, prior to the publication of applicant's application. Is this correct? With regard to the structural limitations of the claims (as all the instant claims are apparatus claims, the use applicant intends to put the claimed device to, or the uses for which it is designed are in and of themselves of little moment, except as those particular uses are uniquely manifested in the claimed structure.). Traditionally in patent law, the claims read over the art when the art fails to meet one of the claimed limitations. However, one requirement here is that the limitation actually be claimed. As the examiner has nowhere found any limitation regarding a blunt tip or one that is otherwise not configured to pierce cut or disrupt tissue, arguments based on this attribute do not serve to distinguish over the art. Further, as the reference to Rizoio et al teaches the exact cutting mechanism (fluid droplets rapidly heated by a laser beam in an interaction zone) claimed by applicants, the lack of such teaching in the secondary reference to Paolini, which is only used for the tip configuration of the cannula, is of little consequence. Similarly, applicant's newly found use of rotating the cannula while advancing it (of which no mention whatsoever is made in the originally filed specification), does not serve to render unobvious the configuration which is well within the scope of one having ordinary skill in the art, and which would be motivated by the ability to incrementally remove tissue, as set forth in the final office action. With regard to the issue of applicant's disagreement with the examiner's assessment that Paolini can be used for removal of fat tissue in joints, the examiner must respectfully note that the entire purpose of Paolini is to remove fat tissue (see the first sentence of the Abstract), and given that the probe has a diameter of about 1 mm (see column 3, lines 25-30), there appears to be no rational basis for applicant's to "disagree" that the device is capable of removing fat tissue from joints, and as such, this disagreement, while noted, is not sufficient to compel the examiner "provide a combinable reference that would be considered by one skilled in the art at the time of the invention to teach and to provide such a motivation for such a use", especially, when "such a use" is nowhere claimed, and even if such use were claimed, the presence thereof in an apparatus claim would lend little, if anything, to the structure of the apparatus. Applicant's assertion that the clearly set forth teachings of the claims in the Paolini reference is noted, but is simply not convincing. It may interest applicant to know that 35 U.S.C. 112, fourth paragraph clearly states that a claim in dependant form "specify a further limitation of the subject matter claimed" given that claim 4 of Paolini (dependent on claim 1) recites, in pertinent part "said piercing of the skin is performed with said needle" undeniably shows that the further limitation on claim 1 is that the piercing of the skin is done with the needle. Logically then, the broader claim 1 must include other piercing methods. Given that the only other structure present in the device is the optical fiber and associated laser, the candidates for the broader piercing methods are rather limited, and can only be assumed to be the laser and fiber, even if other methods are able to be used, the fact remains that, absent some clear and detailed showing by applicant why the use of the laser for this purpose is manifestly impossible, the laser is clearly one of the options for piercing. The examiner has not "required" applicants to show criticality for the off axis interaction zone, applicant's are free not to provide any such evidence. However, the fact remains, if applicant is going to rely on a certain feature as the basis of patentability, it must be critical to the invention. Thus applicant's insistence on not asserting criticality to the claimed feature, while simultaneously insisting on the patentability of the device based on this feature, is not convincing..